DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2016

Exactech, Incorporated
Ms. Lindy Knisely
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K093275
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder System 36 mm Glenosphere and Humeral Liners
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: April 26, 2010
Received: April 29, 2010

Dear Ms. Knisely:

This letter corrects our substantially equivalent letter of May 27, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere and Humeral Liners
Special 510(k) – Indications for Use (DRAFT)

Indications for Use Statement

510(k) Number: K093275

Device Name: Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere and Humeral Liner

INDICATIONS FOR USE:
The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Prescription Use __X__ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093275

K093275 (1/3)

Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere and Humeral Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

MAY 27 2010

510(k) Summary of Safety and Effectiveness

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: **Lindy Knisely, RN**
Regulatory Affairs Specialist

Date: **May 26, 2010**

Trade or Proprietary or Model Name(s):
Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere
Exactech Equinoxe Reverse Shoulder System 36mm Unconstrained Humeral Liner (+0mm)
Exactech Equinoxe Reverse Shoulder System 36mm Unconstrained Humeral Liner (+2.5mm)
Exactech Equinoxe Reverse Shoulder System 36mm Constrained Humeral Liner (+0mm)
Exactech Equinoxe Reverse Shoulder System 36mm Constrained Humeral Liner (+2.5mm)

Common Name:
Reverse Shoulder Prosthesis

Classification Name:
Shoulder joint metal/polymer non-constrained cemented prosthesis
(21 CFR 888.3650, Class II, Product Code KWT)
Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented
(21 CFR 888.3660, Class II, Product Code KWS)

Information on devices to which Substantial equivalence is claimed:

510(k) Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K063569	Equinoxe Reverse Shoulder System	Exactech, Inc.

Indications for Use:

Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere and Humeral Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Device Description:

Glenosphere

The proposed Equinoxe Reverse Shoulder System 36mm Glenosphere is a modification to the existing Equinoxe Reverse Shoulder System glenospheres previously cleared in K063569. The 36mm Glenosphere mates with previously cleared Equinoxe Reverse Shoulder glenoid baseplate and the glenosphere locking screw (K063569). The rationale for the modification of the devices is to offer a smaller glenosphere for patients in whom the 38mm glenosphere is too large.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- The same indications for use
- The same design features
- Incorporate the same materials
- The same shelf life
- Are packaged and sterilized using the same materials and processes.

The only modifications to the predicate devices consist of a proposed dimensional change to decrease the radius of curvature on the articulating surfaces of the glenosphere to 36mm, as well as the removal of the extractor cavities on the side of the glenosphere due to size limitations.

Humeral Liners

The proposed Equinoxe Reverse Shoulder System 36mm Humeral Liners are a modification to the existing Equinoxe Reverse Shoulder System humeral liners previously cleared in K063569. The 36mm Humeral Liners mate with previously cleared Equinoxe Reverse Shoulder humeral tray (K063569). The rationale for the modification of the devices is to offer a smaller humeral liner for patients in whom the 38mm humeral liner is too large.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- The same indications for use

Exactech® Equinoxe® Reverse Shoulder System 36mm Glenosphere and Humeral Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

- The same design features
- Incorporate the same materials
- The same shelf life
- Are packaged and sterilized using the same materials and processes.

The only modifications to the predicate devices consist of a proposed dimensional change to decrease the radius of curvature on the articulating surfaces of the humeral liners to 36mm.

Substantial Equivalence of Non-Clinical Performance Data:
Mechanical tests, engineering analyses, and simulated surgical (sawbones) implantations were conducted to demonstrate substantial equivalence to the predicate devices listed above. A summary of these tests and analyses are as follows:

- A Finite Element Analysis of 36mm Equinoxe Glenosphere which simulated the worst-case loading condition and demonstrated the stresses on the device were below the ASTM yield strength.
- A dynamic loading study in which the stability of the Equinoxe 36mm glenosphere and liners was assessed in a polyurethane bone substitute. The study demonstrated that the proposed devices performed as intended at varying degrees of adduction.
- A geometric analysis evaluating the jump distance between the proposed Equinoxe 36mm glenospheres and liners and their predicates demonstrated the devices are expected to provide similar relative stability and range of motion.
- A polyurethane bone substitute validation was performed to assess passive range of motion for the proposed devices. Proper articulation was achieved during this validation.

Substantial Equivalence Conclusion:
Results of mechanical test and engineering analysis referenced in this 510(k) submission demonstrate that the Exactech Equinoxe 36mm Glenosphere and Humeral Liners are substantially equivalent to the cleared predicate devices.